

Appl. No. 09/869,060
Amendment dated: December 27, 2005
Reply to OA of: March 25, 2003

REMARKS

Applicant notes that claims 4-11 and 16-20 are objected to as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or, neither can said claims depend from any other multiple dependent claims. Accordingly, Applicant has amended the claims to more particularly define the invention in view of the outstanding Official Action. Original claims 1-23 have been canceled without prejudice or disclaimer and new claims 24-43 have been added which avoid this objection. Accordingly, it is most respectfully requested that this objection be withdrawn.

Applicant most respectfully submits that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record. It is noted in the Notice of Acceptance mailed February 28, 2002, that copies of the references cited in the SIR have been received. Therefore the references listed on the 1449 should be with the file. Clarification of this in the next Official Action is most respectfully requested.

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered but is most respectfully traversed. The rejection to claims 1-3 has been obviated by the cancellation of these claims. In rewriting the claims, the level of one or ordinary skill in the art has been taken into consideration and it is believed that such a skilled person would find the claims definite. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-3 and 12-15 under 35 U.S.C. 102(b) as being anticipated by Cockbain et al. has been carefully considered but is most respectfully traversed.

Applicant wishes to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently

described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Applicant notes that it has previously been known to conduct assays for homocysteine (Hcy) in clinical samples, but considerable difficulties have been met in attempting to produce commercial homocysteine assay reagents which could be used with automatic assay equipment. In particular, these automatic analyzers require stock solutions of only a small number of separate reagents, which reagents are refilled only occasionally and must thus remain equally active for a period of weeks or months, during which the analyzer is operating. Prior to the present invention, methods for assaying homocysteine required numerous reagents, which were stable only briefly and needed to be made-up and calibrated shortly before use.

The key contribution of the present invention is that the inventor has devised a way in which an assay for homocysteine may be performed using only three, or even only two separate, stable aqueous reagents, by use of a polyhapten and a complex-forming reaction, which may be detected photometrically.

In the claims as now amended, the specific components required for formulating the stable reagents for use in the above method are specified, and furthermore, the allocation of particular components to particular reagent mixtures is now incorporated from page 7 of the application.

Turning to the rejections in sections 3 to 7 regarding claim clarity, the independent claims of the enclosed set have been amended to more clearly indicate the functioning of the invention and to use consistent language throughout. It is believed that the skilled worker would be aware of the function of the enzyme SAH hydrolase, which is referred to in the claim and would readily appreciate that this enzyme catalyses

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the reaction of homocysteine with adenosine to form SAH. This SAH will compete with the SAH hapten moieties of the polyhapten for binding to the primary antibody and thus alter the degree and rate of precipitation of the complex. Thus, the formation of the complex will reflect the concentration of Hcy in the sample. All the key factors required for this assay method are discussed in the application as filed, and are present in the amended claims. Accordingly, it is most respectfully submitted that the new claims are in full compliance with 35 USC 112.

The rejection of claims 1-3 and 12-15 in the Office Action as fully anticipated by WO 93/15220 has been carefully considered but is most respectfully traversed in view of the amendments to the claims as fully supported by the specification as would be appreciated by one of ordinary skill in the art to which the invention pertains.

Specifically, although this reference provides a method for assaying homocysteine and discloses the use of SAH hydrolase, there is no consideration of the application of this method to automated assay systems and thus the methods disclosed require a larger number of reagents of lower stability than could be accepted for such uses. The citation thus cannot anticipate the present claims.

Furthermore, there is insufficient teaching present to allow the development of a set of reagents which could be used in an automated analyser because the questions of number and stability of reagents are not addressed. The question of which of the various components may or may not be combined to provide suitable reagents is not considered, and thus a skilled worker cannot be taught an assay method falling within the claims as amended herewith. The present claims are thus not obvious in view of this citation. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Finally to the question of the citations from the IDS, Applicant wishes to point out to the Examiner that EP 0483512 has an English equivalent in US 6,210,975. With regard to JP 04329357, the English abstract is enclosed herewith for the Examiner's attention.

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In view of the above comments and further amendments to the claims favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: Richard E. Fichter
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, Fourth Floor
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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EUROPEAN PATENT OFFICE

Patent Abstracts of Japan

PUBLICATION NUMBER : 04329357
PUBLICATION DATE : 18-11-92

APPLICATION DATE : 01-05-91
APPLICATION NUMBER : 03193768

APPLICANT : SHINOTESUTO:KK;

INVENTOR : MOTONAGA HIDEO;

INT.CL. : G01N 33/536

TITLE : IMMUNOLOGICAL MEASURING METHOD

ABSTRACT : PURPOSE: To prevent a disturbance caused by a nonspecific reaction by adding at least one kind of urea, thiocyanate and hydrochloric acid guanidine into a reagent at the optimum concentration in the immune nephelometry.

CONSTITUTION: A sample is added to a reagent, the turbidity of an immune composite body is measured and compared with the turbidity measured in advance to obtain antigenic concentration in the immune nephelometry, and at least one kind of urea, thiocyanate and hydrochloric acid guanidine is added into the reagent at the optimum concentration to prevent a nonspecific reaction. An antigen measurable by the immune nephelometry is used, and sodium thiocyanate is used for the thiocyanate, for example. The optimum concentration differs according to the type of antigens and the type of chemicals, in the measuring system of CRP, for example, the optimum concentration is set to 0.25-0.75mol/L for urea, 0.09-0.31mol/L for sodium thiocyanate, 0.09-0.48mol/L for hydrochloric acid guanidine, and a nonspecific reaction can be suppressed by adding them.

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